that the therapeutic substance is uniformly dispersed throughout the polymeric matrix. This polymeric matrix is composed of an erosion-promoting agent such as starch and a release-controlling agent such as cellulose acetate derivatives, and it does not contain a surface coating layer. It is specifically stated that "*the medicament tablets so produced exhibit superior controlled-release characteristics...and can accept print directly on the finished product without treatment with waxes, coating, or polishing*" (column 6 lines 4-8). Dunn et al. teach the preparation of a sustained release matrix tablets but remain completely silent on the preparation of coated granulated tablets.

Therefore Dunn et al. do not teach nor suggest the process leading to the coating of a granulated therapeutic substance.

Secondly, the person skilled in the art would find no incentive to combine Dunn et al. with Carli and al. In fact, the solvent used in Dunn et al. allows the manufacturing of a matrix wherein all ingredients are homogeneously dispersed (column 5 lines 59-61). In contrast, Carli et al. employs the organic solvent or solvent mixtures in the context of a coating process that allows the different polymers of the coating layer to be sprayed (column 4 lines 20-34). Given that the function of the solvent is different in both documents, a person skilled in the art would have no incentive to combine the 2 documents and adapt the use of the organic solvent of Dunn et al. to the coating process of Carli et al.

Furthermore, even if the person skilled in the art would combine the teaching of both Dunn et al. and Carli et al., he will never obtain the coated granulated ibuprofen according to the invention.

In fact, both references disclose a sustained-release formulation while the present invention has been directed toward the manufacture of a fast-release formulation releasing 80 % of ibuprofen in 30 minutes (page 4 lines 3-5, claim 1).

The person skilled in the art knows of the significant differences between fast-release and sustained-release formulations, in particular in terms of qualitative and quantitative compositions of coating: a coating appropriate for sustained-release formulation is not appropriate for a fast release formulation. In the sustained-release system, the therapeutic substance is made available over an extended period of time after administration, which means that the sustained-release coating is designed to release the active principle over a period of time at different pH medium corresponding to different parts of digestive tracts. On the contrary, the coating according to the invention is specifically designed to improve the palatability of the

ibuprofen while dissolving rapidly and allowing for immediate availability of the ibuprofen upon reaching the gastric medium.

These documents relate to formulations having very different properties, i.e. sustained-release system without masking the acrid taste of the active principle. There is absolutely no reason to take them into account when evaluation the inventive step of the instant invention.

The tablets according to Dunn et al. are characterized by slow and steady erosion from which the therapeutic substance leaches out. The release of the therapeutic substance is only 17% after 30 min and 66 % after 4 hours (Example 38, column 16).

Similarly, the sustained-release compositions of Carli et al. are formulated to maintain an extended bioavailability of the active substance from a few hours up to 24-48 hours or more (column 2 line 59). This is exemplified by the fact that the dissolution rate of the therapeutic substance-loaded particles, which are coated with a blend of ethylcellulose, hydroxypropyl methyl cellulose and colloidal silica, reaches 75 % only after 7 hours (Example 10).

Aside from modifying the release of a drug, the coating layer can make it more palatable by efficiently masking the unpleasant taste of the therapeutic agent and preventing throat irritation when the medication is ingested. The ability to mask a bitter taste is critical for oral formulation, especially for those that are fast-release.

Neither Dunn et al. nor Carli et al. address the issue of palatability.

In fact, the benefit of taste masking adds an additional level of complexity in the development of the fast-release tablets according to the invention.

This problem of palatability is addressed by Myers et al but the solution provided by Myers et al neither describes nor suggests the solution according to the invention.

In fact, Myers et al. teaches the use of sweeteners in fast-release formulations to cover the bitterness of therapeutic agents such as ibuprofen. However, in the present invention the taste masking of ibuprofen is achieved through a completely different approach that involves the coating of granulated microcrystals of ibuprofen with a specific blend of cellulose and/or acrylic polymers.

The cited documents either taken alone or in combination would never allow the person skilled in the art to obtain the fast-release formulation of ibuprofen according to the invention.

The instant claims 10-18, 20 & 21 thus do not contravene 35 USC §103.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,
COHEN & POKOTILOW, LTD.

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By _____
Alan H. Bernstein
Registration No. 19,315
Customer No. 03000
(215) 567-2010
Attorneys for Applicants

Please charge or credit our Account No. 03-0075 as necessary to effect entry and/or ensure consideration of this submission.